UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

MORRIS & DICKSON CO., LLC	CIVIL ACTION NO. 18-cv-00605
v.	JUDGE ELIZABETH E. FOOTE
JEFFERSON B. SESSIONS, III, ET AL	MAGISTRATE JUDGE HORNSBY

MEMORANDUM IN SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY INJUNCTION

Frank H. Spruiell, Jr., La. Bar No. 1611
Reid A. Jones, La. Bar No. 34611
WIENER, WEISS & MADISON
A Professional Corporation
333 Texas Street, Suite 2350 (71101)
P. O. Box 21990
Shreveport, Louisiana 71120-1990
Telephone: (318) 226-9100
Facsimile: (318) 424-5128
Email: fspruiell@wwmlaw.com
Email: rjones@wwmlaw.com

Jodi Avergun (*pro hac vice*), N.Y. Bar No. 2166668
CADWALADER, WICKERSHAM & TAFT LLP
700 Sixth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 862-2200
Facsimile: (202) 862-2400
Email: jodi.avergun@cwt.com

Counsel for Morris & Dickson Co., LLC

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

PAGE(S)

CASES:

STATUTES & OTHER AUTHORITIES:

MAY IT PLEASE THE COURT:

Pursuant to this Court's Temporary Restraining Order ("TRO"), dated May 8, 2018, Plaintiff Morris & Dickson Co., LLC ("Morris & Dickson"), submits this Memorandum in Support of its Motion for Preliminary Injunction enjoining defendants Jefferson B. Sessions, III, in his official capacity as Attorney General of the United States, the United States Department of Justice, Robert W. Patterson, in his official capacity as Acting Administrator of the Drug Enforcement Administration, and the United States Drug Enforcement Administration (the "DEA," and collectively, the "Defendants") from enforcing their Order To Show Cause And Immediate Suspension of Registration, dated May 2, 2018 (the "Immediate Suspension Order" or "ISO"), and an order granting any other relief the court deems just and proper.

PRELIMINARY STATEMENT[1]

On May 8, 2018, following an extensive hearing, this Court issued a Temporary Restraining Order to prevent DEA from enforcing the ISO against Morris & Dickson's license to distribute controlled substances. In issuing the TRO, this Court heard testimony and determined that Morris & Dickson demonstrated a "substantial likelihood" of successfully proving that the Acting Administrator's decision to issue the ISO was arbitrary and capricious. The Court also determined that Morris & Dickson faces a substantial threat of irreparable harm if enforcement of the ISO is not enjoined and that the balance of equity and public interest further weigh in favor of enjoining the ISO's enforcement.

Nothing in the record has materially changed since the issuance of the TRO. In fact, the only development since the TRO hearing was Defendants' submission of a "Partial Administrative Record" that is both incomplete and flouts this Court's order. Rec. Doc. 16.

[1] "Rec. Doc." refers to Electronic Case Filing system docket numbers in 18-cv-00605. Plaintiff hereby incorporates all arguments and evidence referenced or submitted in this action.

Acknowledging the improper tactics employed by Defendants, this Court deemed the Partial Administrative Record to be the complete record and foreclosed any opportunity for DEA to supplement the record. Rec. Doc. 20. The Partial Administrative Record filed by Defendants provides no evidence that changes the Court's prior calculation. Accordingly, for the same reasons that the TRO issued, this Court should grant Morris & Dickson's request for a preliminary injunction.

First, Morris & Dickson is likely to succeed on the merits of its claims. The Partial Administrative Record submitted by DEA fails to demonstrate facts sufficient to justify the conclusion that Morris & Dickson's continued registration poses an imminent danger to public health or safety. DEA relied on faulty methodology and incomplete data to arrive at its conclusions. Its approach to identifying *potentially* suspicious orders has significant statistical and conceptual flaws. As a result, at least 70% of the orders identified by DEA were erroneously designated as "unusually large" and thus "potentially suspicious." Accordingly, DEA arbitrarily and capriciously resorted to the most radical tool in DEA's kit, foregoing more narrowly-tailored options and disregarding DEA's duty, among others, to protect and ensure the legitimate medical supply chain.

Second, Morris & Dickson will suffer irreparable harm without a preliminary injunction. Defendants *conceded* that if Morris & Dickson cannot legally distribute controlled substances from its only distribution center, it will lose its customer base and ultimately shut down — taking close to 800 jobs with it. Defendants also concede that Plaintiff's harm is irreparable because a vindicated Morris & Dickson will not be able to recover compensatory damages from an agency shielded by sovereign immunity.

Third, the balance of hardships favors Morris & Dickson because, in contrast to the existential threat the ISO poses to Morris & Dickson, a preliminary injunction and a modest delay pending an administrative hearing would not harm DEA or the public or result in injustice.

Fourth, the public interest favors injunctive relief to protect healthcare providers' access to pharmaceuticals for legitimate medical reasons and to protect the rule of law against administrative overreach. For these reasons, as well as those set forth below, Morris & Dickson respectfully requests that this Court grant its motion for Preliminary Injunction.

BACKGROUND

A. The United States Drug Enforcement Regulatory Scheme

The Controlled Substances Act and its implementing regulations (the "CSA") restrict the import, export, manufacture, and distribution of controlled substances. 21 U.S.C. § 801 *et seq.*; 21 U.S.C. § 951 *et seq.*; 21 C.F.R. Pt. 1300 *et seq.* The CSA establishes a closed system of distribution, and no person or entity can participate in this closed system without being registered with the DEA and becoming subject to its regulatory scheme. 21 U.S.C. § 822(a); 21 C.F.R. § 1301.11. DEA must enforce the CSA in a balanced manner, preventing the diversion of controlled substances from legitimate channels while ensuring their availability for legitimate medical purposes. 76 Fed. Reg. 39,318 (July 6, 2011).

To further that purpose, the CSA authorizes DEA to revoke, restrict, or suspend a registration upon a determination by DEA that the registration is inconsistent with the public interest. 21 U.S.C. § 824(a)(4). But first, DEA must satisfy notice and due process requirements and procedures under the CSA and applicable law. *Id.* § 824(c). Only under limited circumstances may DEA sidestep these typical procedures and issue an ISO without providing a registrant with prior notice or an opportunity to respond to DEA's allegations. An ISO is only

permitted in cases where the Administrator finds that a particular registration poses an "imminent danger" to the public health and safety. 21 U.S.C. § 824(d). The ISO remedy is thus reserved for only the most egregious cases. Indeed, DEA has used the remedy sparingly. This case marks the first time in over five years that DEA has sought to immediately suspend a distributor's registration.

As part of the closed system of distribution, registrants must file reports to DEA's Automation of Reports and Consolidated Orders System ("ARCOS"). Morris & Dickson files its ARCOS reports on a monthly basis for all transactions of, *inter alia*, controlled substances listed in Schedule II of the CSA. *See* Ex. 1 (TRO Hr'g. Tr.) at 115:25-117:4; 21 C.F.R. § 1304.33. Morris & Dickson files its ARCOS reports automatically. Ex. 1 at 116:7-12. In addition, the law also requires Morris & Dickson to file with DEA a separate report on Form 222 of each distribution of a Schedule I or Schedule II controlled substance. In total, DEA collects some 80 million transaction reports every year from manufacturers and distributors of prescription drugs. 21 C.F.R. § 1305.03; 21 C.F.R. § 1305.13.[2]

B. **Morris & Dickson And Its Shreveport Distribution Facilities**

Morris & Dickson is a drug distribution company headquartered in Shreveport, Louisiana. Ex. 1 at 14:6-10. It was founded in 1841, remains a family-owned and operated business, and is now the sole remaining independently-owned and privately-held full-line drug wholesale distributor in the nation. *Id.* at 12:12-24. Morris & Dickson holds two DEA licenses:

[2] *See also* Jefferson B. Sessions, Att'y Gen., U.S. Dep't of Justice, Remarks on Efforts to Reduce Violent Crime & Fight the Opioid Crisis (Jan. 30, 2018), *available at* https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-efforts-reduce-violent-crime-and-fight-opioid. The Court may take judicial notice of government notices and news media. *See GE Co. v. W. Feliciana Parish Hosp. Serv. Dist. No. 1*, 2016 WL 7007504, at *4 n.11 (M.D. La. Nov. 29, 2016) ("this Court may take judicial notice of publically-available documents and transcripts produced by a state or federal agency which were matters of public record directly relevant to the issue at hand. . . . [And] of stories in newspapers and on Internet news sites." (internal quotation marks omitted)).

one for its sole distribution center in Shreveport, Louisiana, which ships 100% of its drug products, and the second for its small transportation hub in Jefferson Parish, Louisiana. *Id.* at 73:7-74:10. Morris & Dickson employs approximately 787 people, approximately 500 of them in Shreveport. *Id.* at 17:3-10.

Morris & Dickson's Shreveport distribution center provides much-needed drugs to hundreds of hospitals, pharmacies, and alternate care providers—such as nursing homes, hospices, and public health facilities—across 17 different states. *Id.* at 19:1-25. Morris & Dickson services 30-40% of the hospital drug market in Louisiana and Texas alone.[3] *Id.* at 21:2-13. These customers require prompt delivery of controlled substances for thousands of oncology, surgery, urgent care, emergency room, and hospice care patients.

The sale of controlled substances is a small portion of Morris & Dickson's total business. Between January 2014 and September 2017, controlled substances represented only 20.31% of total dosage units sold, and hydrocodone and oxycodone represented only 5.81% of total dosage units sold by Morris & Dickson. Ex. 3 (Morris & Dickson Dosage Unit Sales, admitted at TRO Hearing (Ex.1 at 78:13-20, 140:6-25)).

Morris & Dickson has a multi-faceted system for monitoring and detecting suspicious orders of controlled substances. Morris & Dickson's proactive approach to combatting potential diversion of drugs includes, among other things, (a) screening new pharmacy customers, (b) aggressively monitoring controlled substances orders, and (c) eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, who accept a disproportionate share of cash payments, who prescribe the "Holy Trinity" drug regimen (opioids,

[3] Some of the Louisiana and Texas hospitals that depend on Morris & Dickson's services include University Health Center and Willis Knighton Health Systems in Shreveport; Children's Hospital, Touro Infirmary, University Medical Center, and Jefferson Medical Center in New Orleans; Baton Rouge General Hospital; Lafayette General Medical Center; Children's Hospital and University of Texas Southwest Medical Center in Dallas; and Texas Children's Hospital and Methodist Hospital System in Houston.

benzodiazepines, and carisoprodol), or other red flags of potential diversion. Rec. Doc. 19-1 at M&D_DEA0000031.

C. DEA Previous Recent Reviews and Audit of Morris & Dickson

Nearly two years ago, in August 2016, Morris & Dickson invited officials from DEA's Division of Diversion Control to a meeting, including the then-DEA Assistant Administrator for Diversion Control, as well as his deputy and the local DEA Diversion Program Manager. At that meeting, CEO Paul Dickson explained Morris & Dickson's programs for monitoring and detecting potentially suspicious orders of controlled substances. Ex. 1 at 34:1-39:15. Although Mr. Dickson sought feedback, DEA did not provide any comments or criticisms and suggested no changes to Morris & Dickson's compliance programs. *Id.* at 42:2-43:1. DEA also conducted a regular cyclical audit of Morris & Dickson's sales and distributions records and operations in October 2017. Ex. 2 (ISO) ¶ 12. Before the May 2, 2018 ISO, Morris & Dickson never faced any DEA enforcement action, fine, or penalty in its 177-year history. Ex. 1 at 161:14-21. Despite the fact that DEA has in its possession information about all of the Schedule II controlled substances every pharmacy receives from every distributor, DEA did not ever communicate any concerns to Morris & Dickson about any of its customers or its shipment volumes. Nor did DEA ever request that Morris & Dickson voluntarily stop shipments to any particular customer. *Id.* at 118:20-24.

D. Facing a National Opioid Crisis and Political Pressure, DEA Issues the ISO

President Donald Trump has declared the abuse of opioids a national health emergency. Ex. 2 at 2 n.2. DEA has been widely criticized for what is perceived to be its lackluster response to the opioid crisis. For instance, the Inspector General of the Department of Justice is assessing whether DEA's "regulatory activities and enforcement efforts effectively prevent the diversion of controlled substances, particularly opioids, to unauthorized users," including "enforcement

policies and procedures to regulate registrants."[4] In addition, numerous reports have criticized the DEA for its perceived lax enforcement on drug distributors.[5] In response, DEA and DOJ have engaged in a flurry of activity, including announcing a reduction of quotas for opioid medications, and increased sharing of ARCOS information with industry participants.[6] Most ominous for Morris & Dickson, in a speech on February 27, 2018, the Attorney General announced the Prescription Interdiction and Litigation Task Force, specifically designed to target opioid manufacturers and distributors.[7]

On May 3, 2018, without warning or advance notice, DEA issued its first ISO against a distributor since 2012. Ex. 1 at 162:17-162:18. The ISO immediately cancelled both of Morris & Dickson's DEA licenses, RM0314790 and RM0335732, and required it to *immediately* halt shipment of *all* controlled substances from its Shreveport distribution center. Ex. 2 at 15 The ISO primarily focused on the distribution of hydrocodone and oxycodone to eight independent retail pharmacies from Morris & Dickson's Shreveport center. DEA made no allegations about shipments of other controlled substances, nor were there allegations about any shipments to other classes of customers besides independent retail pharmacies. The ISO was also devoid of allegations about Morris & Dickson's second location in Jefferson Parish. Yet, the ISO stopped

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4 U.S. Dep't of Justice, *Ongoing Work* at 6, https://oig.justice.gov/ongoing/all.htm (last updated Apr. 2018).

5 *See* Lenny Bernstein & Scott Higham, Investigation: *The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; *60 Minutes: Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, (CBS television broadcast Oct. 15, 2017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress

6 Press Release, DEA, DEA Proposes Reduction to Amount of Controlled Substances to be Manufactured in 2018 (Aug. 4, 2017), https://www.dea.gov/divisions/hq/2017/hq080417.shtml; Press Release, DEA, DEA creates new resource to help distributors avoid oversupplying opioids (Feb. 14, 2018), https://www.dea.gov/divisions/hq/2018/hq021418.shtml,.

7 Jefferson B. Sessions, Att'y Gen., U.S. Dep't of Justice, Attorney General Sessions Delivers Remarks Announcing the Prescription Interdiction and Litigation Task Force (Feb. 27, 2018), *available at* https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-prescription-interdiction-and

all distributions of all controlled substances to any class of customer at Morris & Dickson's two registered operations facilities.

The ISO alleges that Morris & Dickson's continued registration constitutes an imminent danger to the public health and safety. *Id.* ¶ 2. The ISO does not allege that Morris & Dickson distributed controlled substances to any unregistered or unapproved entity. Rather, DEA claims that Morris & Dickson "failed to maintain effective controls against the diversion of controlled substances" by (1) allegedly failing to report to DEA "thousands of unusually large orders for hydrocodone and oxycodone" and (2) shipping those orders "without dispelling red flags consistent with diversion." *Id.* ¶ 2; *id.* at 15. DEA did not contend that Morris & Dickson's alleged failures caused any actual diversion.

ARGUMENT

Morris & Dickson is entitled to a preliminary injunction prohibiting Defendants from enforcing the ISO. The decision to grant or deny a preliminary injunction is left to the sound discretion of the district court. *Miss. Power & Light Co. v. United Gas Pipeline*, 760 F.2d 618, 621 (5th Cir. 1985). In order to obtain a preliminary injunction under Fed. R. Civ. P. 65, a plaintiff must show: (1) a substantial likelihood that the movant will prevail on the merits; (2) a substantial threat that irreparable harm will result if the injunction is not granted; (3) that threatened injury absent an injunction outweighs the threatened harm to the defendant if an injunction does issue; and (4) that granting the preliminary injunction will not disserve the public interest. *See La. Dep't of Transp. & Dev. v. U.S. DOT*, 2015 WL 7313876, at *4 (W.D. La. Nov. 20, 2015) (granting injunction enjoining federal agency conduct under Administrative Procedures Act).

Although the movant has the burden of proof on each of these four elements (*id.*), no single element "has a fixed quantitative value. Rather, a sliding scale is utilized, which takes into account the intensity of each in a given calculus." *Tex. v. Seatrain Int'l, S. A.*, 518 F.2d 175, 180 (5th Cir. 1975); *see also Burrell v. U.S. Dep't Agric.*, 2007 WL 438786, at *2 (W.D. La. Feb. 2, 2007) ("The Fifth Circuit applies a sliding scale approach to the balancing of these four factors").

As this Court determined after hearing four hours of argument and testimony on Morris & Dickson's application for a TRO, Morris & Dickson carried its burden of proof on all four of the preliminary injunction factors. Nothing has occurred that should alter the Court's determination. The "Partial Administrative Record"[8] submitted by Defendants only confirms the soundness of the Court's TRO and the grounds for preliminary injunctive relief now.

1. MORRIS & DICKSON IS LIKELY TO SUCCEED ON THE MERITS

Morris & Dickson is likely to succeed on the merits of its claims against Defendants because, even affording DEA its due deference under administrative law, DEA failed to demonstrate that immediate suspension of Morris & Dickson's registrations are necessary to prevent an imminent danger to public health or safety. The Acting Administrator's decision to issue the ISO was arbitrary and capricious and deprived Morris & Dickson of due process.

A. There Is No Imminent Danger To Public Health Or Safety

The CSA only allows DEA to issue an ISO when necessary to protect public health or safety from an "imminent danger." 21 U.S.C. § 824(d)(1). In 2016, Congress defined "imminent danger" in the CSA to mean "a substantial likelihood of an immediate threat that

[8] Defendants' filing of Certification Of Partial Administrative Record (Rec. Doc. 18-1), in which they purport to certify their selectively-disclosed Partial Administrative Record, is vague and ambiguous to the point of being incomprehensible, is non-compliant with the Court's TRO, and is (for these and other reasons) entirely deficient. Morris & Dickson reserves all rights and remedies with respect to Defendants' purported Certification and their Notice Of Filing Of Partial Administrative Record.

death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.* § 824(d)(2). Thus, DEA has no statutory authority to issue an ISO unless the record establishes a nexus between the registrant's alleged violations and an allegedly *imminent* harm or injury without the ISO.

Here, the ISO failed to satisfy the statutory imminence requirement. DEA requires Morris & Dickson to submit its sales data of Schedule II controlled substances through monthly ARCOS reporting. Despite relying on sales data from January 2014 to September 2017, DEA did not take action until now. Ex. 1 at 159:9-12. The Fifth Circuit has found danger was not imminent where DEA delayed less than it did here. In *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 828 (5th Cir. 1976), the Fifth Circuit held that where there was a seven month delay in taking action, there was no "[g]enuine apprehension of imminent danger to the public health and safety." *Id.*; *see also* Ex. 4 (Memorandum & Order in *PRSI Acq. Grp., LLC v. Ashcroft*, No. 02-cv-1020 (D.D.C. May 30, 2002)), Rec. Doc. 8 at 2-3 (preliminary injunction granted where the ISO "does not explain why, if the violations were indeed urgent, DEA waited so long to act on its concerns or why it failed to discuss all of those concerns with the company during the interim."). DEA's delay responding to the drug orders at issue undermines its claim of imminent danger, and is itself sufficient grounds to grant the preliminary injunction.

In addition, Defendants cannot point to any record evidence relied on by the Acting Administrator in finding a "substantial likelihood" of an "immediate threat" of death, serious bodily harm, or abuse.[9] The only facts supporting DEA's conclusions in the ISO and the Partial Administrative Record are that eight of Morris & Dickson's pharmacy customers (three of which

[9] Notwithstanding the DEA's assertions that the ISO is a "non-exhaustive summary" of facts considered by the Acting Administrator (Rec. Doc. 9 at 6), there is nothing in the record to suggest that the Acting Administrator himself—as opposed to other individuals employed by the DEA—considered information summarized in the ISO, let alone any additional facts not expressly referenced in the ISO on which Defendants may now seek to rely.

are no longer customers) purchased an allegedly atypically-high volume of hydrocodone and oxycodone, and that Morris & Dickson shipped drugs to these customers notwithstanding so-called "red flags." Ex. 2 ¶¶ 18-19, 22; *see also* Rec. Doc. 9 at 6. But neither the ISO nor the Partial Administrative Record offers evidence of an immediate threat of death, serious bodily harm or abuse. Indeed, the Partial Administrative Record is devoid of evidence that even a single dosage unit distributed by Morris & Dickson was ultimately diverted. Thus, Morris & Dickson will likely prevail on its claim that no imminent threat exists.

Morris & Dickson poses no threat to public health or safety. In *Bates Drug Stores, Inc. v. Holder*, 2011 WL 1750066 (E.D. Wash. May 6, 2011), the court enjoined enforcement of an ISO in light of "serious doubts that the alleged violations, which [registrant] has been diligently working to correct, pose an *imminent* danger to public health and safety." *Id*. at *3 (emphasis in original). As with Morris & Dickson, in *Bates Drug Stores*, DEA presented "nothing in the record indicating that any . . . patient has been harmed or injured by the alleged violations. Nor [was] there any evidence that any controlled substance was dispensed to an improper individual, for an improper purpose, or in an improper dosage." *Id.*

Morris & Dickson uses a four-fold approach to monitor all prescription drug orders and detect potentially suspicious orders of controlled substances and other drugs: Morris & Dickson (i) retains a third-party company to analyze pharmacy customer ordering practices, which Morris & Dickson uses to flag certain customers for additional analysis; (ii) analyzes ratios of controlled substances to other prescriptions drugs ordered and investigates ratios exceeding expected ranges; (iii) uses internally-developed proprietary software to detect potentially excessive orders of controlled substances and notify internal compliance personnel; and (iv) employs personnel with experience and training specifically tailored to prevent diversion of controlled drugs. Ex. 1 at 187:15-187:24.

In stark contrast to this case, courts have found an "imminent danger" to support an ISO where there was recidivism and violation of binding compliance obligations with the DEA (*Cardinal Health v. Holder*, 846 F. Supp. 2d 203 (D.D.C 2012)), manipulation of records to conceal suspicious orders (*Keysource Med., Inc. v. Holder*, 2011 WL 3608097, at *4 (S.D. Ohio Aug. 16, 2011)), or failures to maintain records regarding drug losses and theft (*Easy Returns Worldwide, Inc. v. U.S.*, 266 F. Supp. 2d 1014, 1019 (E.D. Mo. 2003); *In re Burka*, 684 F. Supp. 1300, 1305 (E.D. Pa. 1988)). No conduct similar to these egregious cases amounting to "imminent danger" is even suggested against Morris & Dickson.

B. The Acting Administrator's Decision To Immediately Suspend Morris & Dickson's Registrations Was Arbitrary And Capricious

Morris & Dickson is also likely to succeed on the merits because the Acting Administrator's decision to issue the ISO was arbitrary and capricious. There is no rationale for the ISO, and it is not narrowly tailored to address the alleged issue of diversion. DEA's immediate suspension of a company's license or registration is governed by the Administrative Procedures Act (the "APA"). *See Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (vacating DEA decision to revoke physician's DEA registration). Under the APA, agency action must be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with applicable law. 5 U.S.C. § 706. Although the arbitrary and capricious standard grants deference to the agency, it is "*by no means a rubber stamp.*" *U.S. v. Garner*, 767 F.2d 104, 116 (5th Cir. 1985) (emphasis added). Indeed, an agency acts arbitrarily and capriciously when it fails to reasonably tailor its actions to fit its stated concerns. *See ILGWU v. Donovan*, 722 F.2d 795, 815-17 (D.C. Cir. 1983) (when an agency elects to take action over "less far-reaching choices," the agency's "failure to consider such alternatives, and to explain why such alternatives were not chosen, was arbitrary and capricious"). To satisfy judicial review under this standard, a federal

agency must explain the rationale for its decisions beyond conclusory statements. *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014).

The record here does not justify the Acting Administrator's unprecedented decision to immediately suspend Morris & Dickson's licenses. Rather, the administrative record, analysis of DEA's statistical methodology, evidence of harmful drug shortages caused by the ISO and even the Acting Administrator's own testimony on May 8, 2018 before the United States House of Representatives Judiciary Committee demonstrates that DEA issued the ISO without the requisite knowledge of the supposed problems the ISO was intended to address. Nor did DEA meaningfully consider the potential impact of immediately suspending Morris & Dickson's registrations.[10] The desire to take action in response to the current national opioid crisis does not on its own provide a foundation for a rational decision-making process. DEA's inability to establish a legitimate rationale for the decision to issue the ISO requires a determination that the Acting Administrator acted arbitrarily and capriciously.

1. DEA's Erroneous Statistical Analysis Further Demonstrates the Arbitrary and Capricious Nature of Its Decision

The ISO's conclusions are primarily based on DEA's mistaken premise that the volumes of controlled substances shipped to the pharmacies named were unusually large, and therefore were suspicious. Ex. 2 (ISO). The ISO's conclusions about suspicious volume of shipments are plainly wrong. *See* Declaration of Kenneth Weinstein dated May 15, 2018 ("Weinstein Decl."). They are based on a methodologically unsound "statistical analysis" of amounts of hydrocodone and oxycodone sold by Morris & Dickson over a period of three years and nine months. Ex. 2 ¶ 18. The Partial Administrative Record reveals that DEA claims to have applied the classic

[10] *Challenges and Solutions in the Opioid Abuse Crisis: Hearing Before the H. Comm. on the Judiciary*, 115th Cong., 2d Sess. (2018) (statement of Robert W. Patterson, Acting Administrator, Drug Enforcement Administration), *available at* https://judiciary.house.gov/wp-content/uploads/2018/05/Patterson-Testimony.pdf.

Tukey methodology of statistical sampling in evaluating Morris & Dickson's sales. M&D_DEA 0000017-18. In fact, a review of the Partial Administrative Record by Kenneth Weinstein, an expert statistician well-versed in the Tukey method reveals that DEA misapplied the Tukey method by modifying the accepted methodology in a way that is not scientifically sound or justified. *See* Weinstein Decl. ¶¶ 9-10.

As Morris & Dickson's expert will demonstrate at the preliminary injunction hearing, DEA has failed to provide a methodologically sound analysis that would reveal a substantial threat of diversion. In particular, when the correct Tukey methodology is applied, the volume of potentially suspicious orders of oxycodone shipped by Morris & Dickson falls by more than 9,000, or nearly 60%, of the 16,596 orders identified as suspicious by DEA. *Id.* ¶ 11. The volume of potentially suspicious hydrocodone orders would fall by more than 1,700, or over 25%. *Id.* ¶ 11.

Even more revealing, once the correct methodology is applied, and limited to orders made in the year prior to the given order date, for 2017 orders identified by DEA as unusually large, *over 70%* of the oxycodone and *over 70%* of the hydrocodone orders would not exceed the unusually large threshold. *Id.* ¶ 17.

In addition, the Partial Administrative Record demonstrates DEA's failure to consider any other factors other than volume shipped. Rec. Doc. 19-1. DEA is supposed to consider a totality of circumstances when deciding to issue an ISO. In particular, DEA failed to consider ordering and inventory practices common to the pharmaceutical business, whether customers are known, and whether any customers have engaged in diversion.

The errors in DEA's statistical analysis methodology skewed the results in favor of DEA's desired outcome. The record demonstrates there is no basis to find Morris & Dickson shipped a large number of suspicious orders. Thus, there is no foundation for DEA's allegations

of CSA violations. When this lack of objective data and incorrect methodology is coupled with the Department of Justice's pre-announced targeting of distributors (*see supra* at 6-7), it necessitates a finding that the DEA's conclusions are arbitrary and capricious.

DEA's analysis is further plagued by its failure to acknowledge that in the last six months, Morris & Dickson's shipments of hydrocodone and oxycodone decreased overall, and shipments also significantly decreased to the pharmacies listed in the ISO. Specifically, sales of hydrocodone and oxycodone to Folse Pharmacy decreased by 33%, to Bordelon's Super-Save Pharmacy by 14%, and to Dave's Pharmacy by 6%. *See* Rec. Doc. 3 ¶ 12.

2. DEA's Failure to Consider Alternative Actions was Arbitrary and Capricious.

The ISO was arbitrary and capricious for the additional reason that DEA failed to consider more narrowly tailored remedies or explain why actions alternative to the ISO would not address its suspicions regarding the volume of certain Morris & Dickson shipments. *See ILGWU*, 722 F.2d at 815-17. By unnecessarily resorting to the most radical remedy available under the CSA, DEA denied healthcare providers and patients access to drugs for legitimate medical purposes — an important aspect of DEA's duties under federal regulations. The ISO precludes Morris & Dickson from shipping *all* controlled substances, but nothing in the administrative record reflects DEA's concern for the potential harm to the public health as the result of sales of drugs other than oxycodone and hydrocodone. As an alternative, DEA could have informed Morris & Dickson about its customers who were potentially diverting controlled substances. DEA also could have directly addressed the issue by suspending the licenses of the registered customers that purportedly made "unusually large" orders and were hypothetically responsible for diverting drugs to unlicensed users. The record lacks any evidence that the Acting Administrator considered more narrowly tailored actions and fails to explain in the ISO

why DEA did not take such alternative actions, demonstrating the arbitrary and capricious nature of the decision.

2. MORRIS & DICKSON WILL SUFFER IRREPARABLE INJURY ABSENT THE REQUESTED RELIEF

Absent a preliminary injunction enjoining Defendants from enforcing the ISO, Morris & Dickson will suffer irreparable harm. "'An injury is irreparable only if it cannot be undone through monetary remedies.'" *Miss. Power*, 760 F.2d at 629 (citations omitted). The injury threatening Morris & Dickson is irreparable because (1) it threatens the very existence of the company, (2) Defendants enjoy sovereign immunity so any monetary damages will not be recoverable, and (3) reputational damage will be immeasurable. At the hearing on the TRO, Morris & Dickson presented detailed evidence showing that a crippling injury to its business is more than likely. Indeed, this had already begun before this Court granted the TRO. Despite lengthy cross-examination, Defendants ultimately conceded irreparable harm.

A. Enforcement of the ISO Threatens the Very Existence of Morris & Dickson.

It is well settled that "economic loss that threatens the survival of a movant's business amounts to irreparable harm." *Power Mobility Coal. v. Leavitt*, 404 F. Supp. 2d 190, 204 (D.D.C. 2005); *see also Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) ("Recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business."); *Cardinal Health*, 846 F. Supp. 2d at 211; *cf. Teladoc, Inc. v. Tex. Med. Bd.*, 112 F. Supp. 3d 529, 541-42 (W.D. Tex. 2015) ("destruction of a business model may constitute irreparable injury").

This Court has already found "that Morris & Dickson faces a substantial threat of irreparable harm if the immediate suspension of DEA Certificates of Registration . . . is not enjoined" for two weeks pending a full hearing on the preliminary injunction. Rec. Doc. 16. In

reaching its finding, this Court expressly acknowledged Defendants' *concession* of irreparable harm. Ex. 1 at 196:13, 177:14-17.

Its finding are well-supported. Mr. Dickson credibly testified that it was "absolutely certain" that, if the ISO remained in effect, Morris & Dickson "will be extinguished. It will be knocked out. We'll lose 80 percent of our business. We cannot survive on 20 percent." *Id.* at 68:21-69:7, 70:19-24. Morris & Dickson's fixed overhead cannot be reduced overnight; it has liabilities in the form of a 500,000 square foot facility, a fleet of trucks, and 787 employees with a payroll of over $58 million. *Id.* at 17:3-24, 70:21-24. Thus, the economic harm posed by the ISO "threatens the very existence of the movant's business." and therefore is certain, immediate, and irreparable. *Wis. Gas*, 758 F.2d at 674. Without a preliminary injunction, Morris & Dickson's 787 employees, 508 of whom work in the Shreveport, Louisiana region, will lose their jobs. Ex. 1 at 17:3-24.

Breaking down the numbers, the devastation to Morris & Dickson will come from losing its customers, likely permanently, if it is unable to fulfill their urgent need for prescription pharmaceuticals, including those subject to DEA regulation. *Id.* at 68:21-69:7, 70:19-21.[11] Even if some customers continue buying non-controlled drugs from Morris & Dickson, its sales would fall dramatically. This would undermine the volume discount Morris & Dickson obtains from its suppliers, leading to a price increase. The price hike would render Morris & Dickson unable to compete in the market. *Id.* at 70:25-71:1-16.

[11] Customers will be unable to use Morris & Dickson as their supplier because common industry practice requires a controlled substance supplier to be the primary supplier to its customer. Ex. 1 at 13:5-14:5, 197:1-197:6. Secondary wholesalers may supply a much smaller percentage of a pharmacy's needs (20% or less) but *they will not, as a regular practice, supply any controlled substances*. *Id.* at 13:23-14:5. The "Big Three" wholesalers *all require* a primary-supplier relationship with pharmacies before selling them controlled substances. *Id.* at 69:2-4. A primary supplier relationship requires the customer to buy both its controlled and non-controlled medications from the primary supplier.

Morris & Dickson also cannot realistically fulfill its agreements with numerous pharmacies and hospitals when it cannot provide controlled substances to satisfy those customers' needs—needs that are frequently urgent and certainly cannot await adjudication of the ISO. In the absence of a preliminary injunction, customers will have grounds to terminate Morris & Dickson's exclusive supply contracts and instead consolidate all their purchases with competing distributors that can serve both controlled and non-controlled substances, resulting in a permanent loss of customers and revenue for Morris & Dickson. *Id.* at 68:21-69:7, 70:19-21.

These injuries to Morris & Dickson are both concrete and certain: in two business days after the ISO was issued and before this Court granted a TRO, Morris & Dickson's total sales fell by 14%. *Id.* at 67:23-68:20. Before this Court could even grant a TRO, Morris & Dickson's largest single customer, representing 10% of total sales, gave notice that it was seeking a new primary wholesaler to replace Morris & Dickson. *Id.* at 69:6-19. This is exactly the sort of injury other courts have found to be irreparable. *See Bates Drug Stores*, 2011 WL 1750066, at *2 (irreparable harm found and TRO granted where the "harm is not speculative: Plaintiff's revenue dropped twenty percent (20%) in the first twenty (20) days following the Suspension Order"). Nothing material has changed to alter the Court's finding.

Unlike nationwide drug distributors involved in prior litigations regarding DEA suspension orders, Morris & Dickson operates from a single warehouse. The ISO would thus bring Morris & Dickson's controlled drug sales to a standstill, because it has no opportunity to fulfill controlled substance orders from alternate registered locations. *Id.* at 73:7-74:9. This fact entirely distinguishes Morris & Dickson's situation from DEA's successful opposition to a preliminary injunction in the *Cardinal Health* and *Holiday CVS* cases.

Unlike *Cardinal Health*, Morris & Dickson does not have "several distribution facilities nationwide that continue to hold DEA registrations" and so is not "free to ship from its other

distribution facilities."[12] *Cardinal Health*, 846 F. Supp. 2d at 211. The presence of multiple alternative distribution sites in *Cardinal Health* was determinative of that courts' decisions to deny preliminary injunction and allow the ISO to take effect. *Id.* The *Holdiay CVS* case is also inapposite. *See Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 172 (D.D.C.), *vacated and remanded on other grounds*, 493 F. App'x 108 (D.C. Cir. 2012) (per curiam) (Unpublished). That case denied a preliminary injunction where CVS, as a national chain, did not depend for its existence on the income of the two specific locations subject to the ISO. Unlike CVS, Morris & Dickson must "live or die based solely on the revenue [it] independently generate[s]." *Id.*

DEA proposes to leave the ISO in effect indefinitely while requiring Morris & Dickson to pursue administrative remedies. Without a preliminary injunction, Morris & Dickson would likely face a delay of a year or more before DEA issues a final determination on whether the ISO was even rightly imposed in the first place. DEA does not even propose to hold a hearing for close to two months—until July 9, 2018—at which Morris & Dickson would have its first chance to refute the mistaken evidence and reasoning behind the ISO. Ex. 2 at 1; *cf.* Ex. 4 at 3 ("Monetary losses threatening the destruction of a business constitute irreparable harm" based on credible evidence that "business will dry up very quickly" pending an initial hearing in four months). In addition, DEA faces no statutory timeline for making a final determination withdrawing the ISO, no matter how resoundingly Morris & Dickson refutes the ISO. *See* 21 U.S.C. § 824(d).

As set forth above, without a preliminary injunction Morris & Dickson will not survive until the July 9 hearing, let alone for a year or more pending an administrative decision to reverse

[12] Morris & Dickson maintains a small backup facility in Jefferson Parish, Louisiana, to process returns and as backup "in case of emergency." Ex. 1 at 74:1-9. The ISO requires the shutdown of operations at both Morris & Dickson's sole operating facility in Shreveport and the backup facility in Jefferson Parish. *Id.* at 122:8-11. Thus, Morris & Dickson cannot preserve its business by relocating shipment activity to an unaffected facility, because it has none. *Id.* at 73:7-13.

the ISO. The rationale employed by this Court in issuing the TRO to prevent irreparable harm for two weeks applies all the more forcefully here, as the evidence continues to justify finding irreparable harm from a suspension that would last *more than 25 times longer* than the two weeks at issue in the TRO.

B. Morris & Dickson's Imminent Injury Is Irreparable.

If a government action threatens great, certain, and imminent injury, that injury is deemed irreparable because sovereign immunity will prevent the recovery of compensatory damages. *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (if plaintiff "cannot recover damages from the defendant due to the defendant's sovereign immunity . . . any loss of income suffered by the plaintiff is irreparable *per se*"); *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 52-53 (D.D.C. 2011); *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 72 (D.D.C. 2010).

In this case, Morris & Dickson faces economic losses, as described above. Defendants' lawyers have conceded that sovereign immunity will be "difficult to get beyond" in this case. Ex. 1 at 77:12-78:12, 196:20-25. Even if the Court finds those losses present a less-than-existential threat to Morris & Dickson's business, the loss is certain, imminent, and entirely noncompensable because DEA's actions are protected by the shield of sovereign immunity. *See Armendariz-Mata v. U.S. DOJ, DEA*, 82 F.3d 679, 682 (5th Cir. 1996) (dismissing compensatory and punitive damages claims against DEA, explaining the "APA's § 702 waiver of the government's sovereign immunity does not apply to monetary damages.").

C. Enforcement of the ISO Poses Irreparable Injury to Morris & Dickson's Reputation.

Irreparable injury is also demonstrated by a loss of goodwill and business reputation. *BellS. Telecomms. v. MCIMetro Access Transmission Servs.*, 425 F.3d 964, 970 (11th Cir. 2005); *Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962); 11A Charles A. Wright, *et al.*,

Fed. Prac. & Proc. § 2948.1 (3d ed. 2018). Courts have found that irreparable harm arises from "the loss of [plaintiff's] customers and by the possibly permanently damaged relationships with its customers." *Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 77-78 (D.D.C. 2001); *Bates Drug Stores*, 2011 WL 1750066, at *2 (DEA action posed "harm to reputation and goodwill").

Morris & Dickson's customers report that they are setting up secondary accounts with competing distributors so that they may switch to a competitor if a preliminary injunction is not granted. Rec. Doc. 10-3 at 2. Before the ISO, few Morris & Dickson customers saw reason to set up secondary accounts. Now, with the threat of sudden cut-off to supply of vital medicines, customers are wary of relying on Morris & Dickson. At least one major hospital has asked this Court to enjoin the effect of the ISO, if not pending a hearing, at least long enough for them to find an alternate supplier to replace Morris & Dickson. Rec. Doc. 21. This reputational harm has therefore already injured Morris & Dickson by allowing competitors to establish relationships with its formerly exclusive customers. Ex. 1 at 69:2-4 (Morris & Dickson's "big three" competitors require a primary relationship before selling controlled substances to a customer). If the ISO is not enjoined, Morris & Dickson's reputation would be indelibly associated with disruption and uncertainty, rather than the reliability that institutional health care customers demand of their suppliers.

3. THE BALANCE OF HARDSHIPS FAVORS MORRIS & DICKSON

Plaintiff can easily demonstrate that the balance of hardships weighs in its favor because "the threatened harm to the plaintiff is greater than that which would threaten the defendant if an injunction issued." *Gearhart Indus., Inc. v. Smith Int'l, Inc*., 592 F. Supp. 203 at 214 (N.D. Tex. 1984) 7, *aff'd in part, modified in part*, 741 F.2d 707 (5th Cir. 1980); *Morris v. Bush*, 1999 WL

58857 (N.D. Tex. Jan. 28, 1999). In contrast to the serious—calamitous—hardship facing Morris & Dickson and its customers in the absence of a preliminary injunction, there is no imminent danger to DEA or to the public if the Court stays the effect of the ISO.[13] Morris & Dickson has already ceased shipments of controlled substances to three of the eight customers identified in the ISO, and it stands ready and willing to suspend shipments to the remaining five, and to any other customer DEA identifies as suspected of engaging in diversion.

The only purported harm the DEA identified was some undefined concern about possibly undermining its authority if it faced judicial review of its otherwise-unchecked "immediate suspension power." Rec. Doc. 9 at 8. But that argument is not unique to this case, and it is an affront the Court's constitutionally-granted powers. Moreover, DEA's own approach to Morris & Dickson evidences no sense of urgency to their action, just a capricious reversal after a long record of silently endorsing Morris & Dickson's diversion controls. Morris & Dickson invited DEA representatives to a presentation of their diversion control methods in August 2016, and solicited DEA's comments and suggestions. DEA offered no criticism, constructive or otherwise. *Id.* at 33:12-37:8, 42:2-43:11. In 2017, DEA audited Morris & Dickson, and again reported no adverse findings regarding diversion control. *Id.* at 39:16-40:21, 131:24-132:19. DEA served subpoenas on Morris & Dickson in February 2018, but DEA provided no feedback regarding diversion controls. *Id.* at 42:1-25, 43:1. Instead, DEA suddenly issued the ISO on May 2, 2018, having never previously notified Morris & Dickson that a single aspect of their diversion control operation was unacceptable. *Id.* at 42:1-7. Having waited three months after issuing subpoenas, six months after conducting an audit, and approximately 21 months after

[13] Contrary to DEA's assertion (Rec. Doc. 9 at 8 n.3), a pharmaceutical supplier *does* have an interest in "providing continued care to its customers in need of medicine, employment to its employees, and support to patients in long-term care and assisted-living facilities," sufficient to outweigh the DEA's interest in unfettered control over the regulation of controlled substances. *Bates Drug Stores*, 2011 WL 1750066, at *3.

learning in detail about Morris & Dickson's diversion controls, DEA can hardly be heard to complain that a few more months under the existing set of safeguards will undermine DEA's deterrent power or pose an imminent threat to public health.

4. THE PUBLIC INTEREST FACTOR HEAVILY FAVORS GRANTING THE PRELIMINARY INJUNCTION

The public interest weighs heavily in favor of granting a preliminary injunction. Morris & Dickson is not accused of actually diverting any controlled substances. The ISO only alleges that certain of its customers could possibly divert commonly diverted drugs. *See Bates Drug Stores*, 2011 WL 1750066, at *3 (continued operation did not threaten public interest where the alleged violations are "correctable and have not harmed any customer, patient or member of the public."); Ex. 4 at 4 ("There is of course a strong public interest in preventing the illegal distribution and use of controlled substances, but DEA has not shown that the risk of future improper diversion is great enough to tip the scale . . . in its favor."). Perversely, the ISO would allow all of Morris & Dickson's customers to resume operation with new distributors, even if the DEA suspects those specific customers are diversion threats.

On the other hand, an injunction serves the public interest because the ISO would *threaten* the public interest by interrupting the supply of vital medication to medical providers and the numerous patients that depend on Morris & Dickson to treat their legitimate medical needs. *All* of Morris & Dickson's customers—hundreds of healthcare providers across 17 states—depend on Morris & Dickson's Shreveport facility to deliver controlled substances to their thousands of patients. Ex. 1 at 18:24-20:23.

If enforced, DEA's suspension will halt the flow of legitimate and medically-necessary drugs to hundreds, if not thousands, of Morris & Dickson's customers, including 30-40% of the hospital drug market in Louisiana and Texas alone. *Id.* at 20-21. Without medicine shipments

from Morris & Dickson, these hospitals and other medical providers will face immediate drug shortages. Many of Morris & Dickson's hospital customers are dependent on receiving next-day and same-day shipments. Rec. Doc. 3 ¶ 16. Thus, enforcement of the ISO will severely disrupt the ability of hospitals and alternate care facilities to obtain critical life-saving medications.

Finally, the public interest is served by preventing DEA from overstepping its statutory authority. *Jacksonville Port Auth. v. Adams*, 556 F.2d 52, 59 (D.C. Cir. 1977) ("there is an overriding public interest . . . in the general importance of an agency's faithful adherence to its statutory mandate"). It cannot be forgotten here that DEA's mandate includes not just preventing diversion but protecting and ensuring the legitimate medical supply chain. DEA, under pressure to reverse years of inaction that led to the nation's current opioid crisis, and acting hastily in response to a DOJ mandate specifically designed *to target* drug manufacturers and distributors, abused its discretion in issuing the ISO. In sum, the strong public interest weighs in favor of granting the requested injunctive relief.

CONCLUSION

For the foregoing reasons, Morris & Dickson respectfully requests that this Court grant its application for a preliminary injunction.

Respectfully submitted,

By: /s/ *Reid A. Jones*
Frank H. Spruiell, Jr., La. Bar No. 1611
Reid A. Jones, La. Bar No. 34611
WIENER, WEISS & MADISON
A Professional Corporation
333 Texas Street, Suite 2350 (71101)
P. O. Box 21990
Shreveport, Louisiana 71120-1990
Telephone: (318) 226-9100
Facsimile: (318) 424-5128
Email: fspruiell@wwmlaw.com
Email: rjones@wwmlaw.com

Jodi Avergun (*pro hac vice*), N.Y. Bar No. 2166668
CADWALADER, WICKERSHAM & TAFT LLP
700 Sixth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 862-2200
Facsimile: (202) 862-2400
Email: jodi.avergun@cwt.com

Counsel for Morris & Dickson Co., LLC

CERTIFICATE OF SERVICE

I certify that on this 15th day of May, 2018, I have served a copy of the above and foregoing on all counsel of record through the Court's CM/ECF system.

s/ *Reid A. Jones*
Reid A. Jones